

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-1016V

Filed: June 2, 2020

UNPUBLISHED

MARYELLEN KOTTENSTETTE and
NICHOLAS KOTTENSTETTE, as best
friends of their daughter (CK),

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Reconsideration; Decision on
Remand; Change in Controlling Law;
Request to File New Evidence;
Infantile Spasms; Seizure; DTP;
DTaP

John F. McHugh, Law Office of John McHugh, New York, NY, for petitioners.

Camille Michelle Collett, U.S. Department of Justice, Washington, DC for respondent.

ORDER ON MOTION FOR RECONSIDERATION¹

After this case was remanded to me by the Court of Federal Claims for issuance of a decision resolving entitlement, I issued a decision dismissing petitioners' claim on April 27, 2020. On May 5, 2020, petitioners moved for a reopening of the evidentiary record on entitlement and a reconsideration of the April 27, 2020 decision on remand. Petitioners' motion is **GRANTED in part and DENIED in part**. I previously withdrew the decision on remand and petitioners' motion is granted to the extent of having withdrawn the prior decision for purposes of considering petitioners' arguments in favor of reconsideration. Accordingly, a superseding decision will be issued pursuant to Vaccine Rule 10(e). However, for the reasons discussed below, petitioners' arguments are unpersuasive and that superseding decision will not reach a different result from the

¹ Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. See 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

original, now withdrawn, April 27, 2020 decision on remand. Moreover, petitioners' request to reopen the record on entitlement is denied.

I. Procedural History

This case was filed on September 11, 2015. It was originally assigned to Special Master Millman, who has since retired. Petitioners initially alleged that their minor daughter, C.K., suffered an encephalopathy following several vaccinations administered on October 2, 2012. Subsequently, petitioners changed their focus with an expert presentation by neurologist Marcel Kinsbourne, M.D., who opined that C.K. experienced vaccine-caused infantile spasms. Special Master Millman issued a ruling on entitlement in petitioners' favor on December 12, 2017, and a decision awarding damages on May 29, 2019. Thereafter, the case was reassigned to me on June 6, 2019.

On June 28, 2019, respondent filed a motion for review of Special Master Millman's ruling on entitlement. On February 12, 2020, the Court of Federal Claims granted respondent's motion, vacated Special Master Millman's ruling on entitlement, and remanded the case to me for further consideration in accordance with the correct legal standard. (ECF No. 130; see *also* 2020 WL 953484 (Fed. Cl. Feb. 12, 2020).) In so doing, the remanding opinion discussed the Federal Circuit precedent of *Boatmon v. Secretary of Health & Human Services*, 941 F.3d 1351 (Fed. Cir. 2019), as clarifying the prior decades-old Federal Circuit precedents that Special Master Millman was found to have misapplied in the instant case.

I issued a decision on remand dismissing petitioners' case on April 27, 2020. (ECF No. 132 (now withdrawn).) I found pursuant to an *Althen* analysis that, although onset of C.K.'s first seizure was temporally proximate to her vaccination(s), petitioners had failed to provide sufficient evidence that a vaccine can trigger a seizure in the absence of other factors of stress or inflammation. One issue discussed in that analysis was that, although petitioners had relied on studies temporally linking infantile spasms to the DTP vaccine, they did not otherwise provide evidence relative to any other vaccines, including the DTaP vaccine. I further found that petitioners' had not carried their burden with regard to *Althen* prong two.

Petitioners moved for reconsideration of my decision on remand on May 5, 2020. (ECF No. 133.) I subsequently withdrew my decision so that petitioners' motion could be considered and ordered respondent to file a response. (ECF No. 134.) Respondent filed his response on May 19, 2020, and petitioner filed a reply on May 26, 2020. (ECF Nos. 135, 137.) Accordingly, petitioners' motion is now ripe for resolution.

II. Party Contentions

a. Petitioners' Initial Motion

Focusing on the remanding opinion's discussion of *Boatmon v. Secretary of Health & Human Services*, petitioners argue that they did not have a "full and fair

opportunity” to present their case because the burden of proof was “adjusted,” and in fact heightened, by the remanding opinion subsequent to Special Master Millman’s closing of the record and resolution of the claim. (ECF No. 133, p. 1-2.) Accordingly, petitioners request an opportunity to submit additional evidence to meet what they characterize as an “increased burden of proof.” (*Id.* at 2.) With their motion, petitioners filed four additional exhibits marked as Exhibits 30-33.² (ECF No. 133-1 *et seq.*) They also cite, but did not file, a 2002 study by Lisa Jackson et al.,³ excerpts from DTaP manufacturer package inserts cited in a prior decision from 2009, and unspecified CDC Vaccine Information Statements relating to DTaP. (ECF No. 133, pp. 8-9.) These materials are submitted to advance petitioners’ assertion that compared to the older DTP vaccine, DTaP “does the same harm only less frequently.” (*Id.* at 6.)

Petitioners also contend that “[w]hile the Court and Respondent focused on the fact that DTaP is not DPT and on the lack of focus in this case on the difference between the two, this child in fact had numerous vaccines that day and the focus was on the effect of vaccines generally not specifically DTaP.” (*Id.* at 2.) Contrasting Dr. Kinsbourne’s opinion against the expert presentation in *Boatmon*, petitioners stress that Dr. Kinsbourne’s opinion was based on his own experience researching the effect of ACTH on the condition of infantile spasms. (*Id.* at 2-3.) Petitioners reiterate several points from Dr. Kinsbourne’s expert reports (*Id.* at 3-5, 13-14) to submit that his opinion “was fully supported by the peer reviewed medical literature cited in his report.” (*Id.* at 6).

Petitioners request that the court “take judicial notice of the fact that DTaP is safer than DTP as it does the same harm less frequently.” (*Id.* at 7.) Citing the above-described, newly-filed materials relating to the DTaP vaccine, petitioners contend that “the fact that pertussis vaccine can cause seizures is generally accepted by the medical community.” (*Id.*)

² Exhibit 30 is an undated print-out of a webpage from UCLA Health Pediatrics suggesting that there are about 2,000 cases of infantile spasms in the U.S. annually. Exhibit 31 is Nicole Le Saux et al., *Decrease in Hospital Admissions for Febrile Seizures and Reports of Hypotonic-Hyporesponsive Episodes Presenting to Hospital Emergency Departments Since Switching to Acellular Pertussis Vaccine in Canada: A report from IMPACT*, 112 PEDIATRICS 5 (2003). Exhibit 32 is Dennis Conrad & Hal Jenson, *Using Acellular Pertussis Vaccines for Childhood Immunization. Potential Benefits Far Outweigh Potential Risks*, 105 POSTGRAD MED 165 (1999); however, there is no information on the face of this document confirming when and where this paper was published. Exhibit 33 is M. Miles Braum et al., *Infant Immunization with Acellular Pertussis Vaccines in the United States: Assessment of the First Two Years’ Data from the Vaccine Adverse Event Reporting System (VAERS)*, 106 PEDIATRICS e51 (2000).

³ Lisa Jackson et al., *Retrospective Population-based Assessment of Medically Attended Injection Site Reactions, Seizures, Allergic Responses and Febrile Episodes after Acellular Pertussis Vaccine Combined with Diphtheria and Tetanus Toxoid*, 21 PEDIATRIC INFECTIOUS DISEASE J. 781 (2002). Only a link to a webpage displaying the abstract was provided. The article itself is not publicly available at that location.

Petitioners conclude that “[t]he connection between pertussis and seizures is so well recognized that this court in particular can and should take judicial notice of that fact.” (*Id.* at 15.) Petitioners further explain that “[t]he record in this case was generated based upon the *Althen* and *Knudsen* standard of proof. This Court has concluded that this burden of proof has been significantly raised to require scientific proof of phenomena medicine believes to exist due to cause and effect. Thus, Petitioner should be given the opportunity to submit such proof or to provide expert opinion as to why science deems the conclusions based upon cause and effect to be sound.” (*Id.*)

b. Respondent’s Response

Respondent raised several points in response to petitioners’ motion. (ECF No. 135.) First, respondent explained why the remanding opinion did not change petitioners’ burden of proof. (*Id.* at 2-4.) Instead, respondent contends that petitioners seek under the guise of legislative intent to reduce their burden to something akin to the more lenient presumption of causation available specifically for Table claims despite presenting a claim based on causation-in-fact. (*Id.* at 3.) Second, respondent disputes that petitioners were denied the opportunity to fully and meaningfully develop the record of this case, noting that petitioners have not identified any evidence that was previously unavailable. (*Id.* at 4.) Finally, respondent asserts that petitioners have not established any manifest injustice and only seek to relitigate a decision with which they do not agree. (*Id.* at 5.)

c. Petitioners’ Reply

In their reply, petitioners contend that “[d]ecisions on entitlement are to be based on the entire record not on language used in a decision. Here the Court based its remand on that language and stated that the record has not been reviewed. The word discussed in the opinion was “plausible” used by Special Master Millman to describe petitioner’s theory of causation.” (ECF No. 137, p. 1.) Petitioners assert that if Dr. Kinsbourne’s report and testimony “are not found to be ‘sound and reliable,’ the standard of proof has been raised beyond the ability of science to comply and all prior instruction from the Federal Circuit on the burden of proof has been nullified.” (*Id.* at 2.)

Petitioners reiterate Dr. Kinsbourne’s opinion that all vaccines cause a release of cytokines and, in turn, that proinflammatory cytokines stimulate corticotropin-releasing factor. (*Id.* at 3.) Petitioners further argue that “the fact that DTaP can cause the same adverse events as DTP, particularly seizures, is so well accepted that petitioners urge that it be judicially noticed.” (*Id.* at 4.)

Petitioners also dispute respondent’s position that petitioners cannot supplement the record at this stage in the proceeding. Citing Section 13(b) of the Vaccine Act, petitioners contend that “[w]hile some of the material relied upon on this motion was not submitted during the entitlement phase of this action, i.e. before December of 2017 . . . the petitioner is authorized by law to supplement the record.” (*Id.* at 5.)

III. Applicable Legal Standard

Vaccine Rule 10(e), which governs motions for reconsideration, provides, “[e]ither party may file a motion for reconsideration of the special master’s decision within 21 days after the issuance of the decision....” Vaccine Rule 10(e)(1). A party seeking reconsideration “must support the motion by a showing of extraordinary circumstances which justify relief.” *Fru-Con Constr. Corp. v. United States*, 44 Fed. Cl. 298, 300 (1999). The motion for reconsideration “must be based ‘upon manifest error of law, or mistake of fact, and is not intended to give an unhappy litigant an additional chance to sway the court.’” *Prati v. United States*, 82 Fed. Cl. 373, 376 (2008) (quoting *Fru-Con Constr. Corp.*, 44 Fed. Cl. at 300).

Generally “[a] court may grant such a motion when the movant shows ‘(1) that an intervening change in the controlling law has occurred; (2) that previously unavailable evidence is now available; or (3) that the motion is necessary to prevent manifest injustice.’” *System Fuels, Inc. v. United States*, 79 Fed. Cl. 182, 184 (2007) (quoting *Amber Resources Co. v. United States*, 78 Fed. Cl. 508, 514 (2007)). Granting such relief requires “a showing of extraordinary circumstances.” *Caldwell v. United States*, 391 F.3d 1226, 1235 (Fed.Cir.2004) (citation omitted), *cert. denied*, 546 U.S. 826, 126 S.Ct. 366, 163 L.Ed.2d 72 (2005). Special masters have the discretion to grant a motion for reconsideration if to do so would be in the “interest of justice.” Vaccine Rule 10(e)(3). It has previously been noted, however, that there is little guidance interpreting Vaccine Rule 10(e)(3) beyond the conclusion that it is within the special master’s discretion to decide what constitutes the “interest of justice” in a given case. See *Krakov v. Sec’y of Health & Human Servs.*, No 03–632V, 2010 WL 5572074, at *3 (Fed. Cl. Spec. Mstr. Jan. 10, 2011) (granting reconsideration of motion to dismiss case for failure to prosecute).

IV. Discussion

a. Petitioners’ Burden of Proof Was Not Heightened and There Has Been No Change in Controlling Law

First and foremost, petitioners argue that reconsideration is warranted because there has been an intervening change in controlling law. Referring to the Federal Circuit’s November 2019 decision in *Boatmon v. Secretary of Health & Human Services*, petitioners argue that “the decision of this Court, on remand, makes it clear that the standard for proof of causation applicable to this matter was ‘clarified by the Federal Circuit after the Special Master’s decision under review.’ Thus, the burden of proof was adjusted after the decision by Special Master Millman.” (ECF No. 133, p. 1.) Petitioners continue “[i]t is apparent from the decision of this Court that it is of the opinion that the *Boatmon* standard has significantly increased the petitioner’s burden of proof.” (*Id.*) This represents the rationale underlying the entirety of petitioners’ motion; however, is incorrect.

The decision on remand, now withdrawn but nonetheless the subject of this motion, applied the causation-in-fact test articulated by the Federal Circuit in 2005 in the decision *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed Cir. 2005). (ECF No. 132, pp. 4-5, 13-26.) The decision on remand cited the more recent *Boatmon* decision only for the proposition that petitioners' theory must be based on a "sound and reliable medical or scientific explanation." (ECF No. 132, p. 5 (quoting *Boatmon*, 941 F.3d at 1359.) However, that aspect of *Boatmon* is a direct quotation of the Federal Circuit's prior *Knudsen* decision, which dates back to 1994, and which was relied upon by Special Master Millman in her earlier ruling on entitlement. See *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d, 543, 548 (Fed. Cir. 1994). In their motion for reconsideration, petitioners likewise confirm that "[t]he record in this case was generated based upon the *Althen* and *Knudsen* standard of proof." (ECF No. 133, p. 15.) Since this is the same standard that was applied in the decision on remand, there is no basis for reconsideration relative to petitioners' burden of proof.⁴

While it is true that the Federal Circuit's *Boatmon* decision was repeatedly referenced in the remanding opinion and post-dates Special Master Millman's decision in this case, it is not accurate that the burden of proof was adjusted based on this discussion. The remanding opinion explained that Special Master Millman misapplied the Federal Circuit's *Knudsen* precedent and failed to engage in a full discussion of the type of analysis dictated by the *Althen* precedent. The remanding opinion stressed that the language of the Federal Circuit's *Knudsen* decision must be understood in the context of its subsequent *Althen* decision, explaining that statements in *Knudsen* "should not be taken to loosen the requirements of *Althen*, which was decided almost 11 years later." (ECF No. 130, p. 8; see also 2020 WL 953484, at *6.) Moreover, the remanding opinion instructed that the case be decided on remand in accordance with the "correct legal standard," which is identified within both the remanding opinion and Federal Circuit's *Boatmon* decision as a showing by preponderant evidence consistent with the *Althen* test. (ECF No. 130, pp. 5, 8; *Kottenstette*, 2020 WL 953484, at *3, 6; *Boatmon*, 941 F.3d at 1358-63.) The gravamen of the remanding opinion was never that the relevant burden of proof changed, only that Special Master Millman misapplied the decades-old Federal Circuit precedents in this instance as further evidenced by the more recent decision in *Boatmon*. In fact, the remanding opinion was explicit in stating that the burden of proof applied by Special Master Millman was lower than what is dictated by *Knudsen* and *Althen*.⁵

⁴ In fact, to the extent any specific holdings of *Boatmon* were discussed in the decision on remand, the instant case was favorably distinguished. (See ECF No. 132, n.22, n.27.)

⁵ Specifically, following a discussion of nine different principles underlying the special master's analysis, the Court stated: "The special master's articulation of these premises, however, suggests they were offered as alternative support for the petitioners' causal theory, which, as discussed above, was plausible or reasonable, but insufficient to satisfy *Althen*'s first prong. The special master appears to have relied on these nine premises to put a thumb on the scale, without explicitly analyzing under *Althen*'s first prong the applicability of the petitioners' causal theory to the vaccine and the kind of injury at issue." (ECF No. 130, p. 7; *Kottenstette*, 2020 WL 953484, at *5.)

In any event, although the Federal Circuit most recently discussed *Althen* and *Knudsen* in *Boatmon*, it did so approvingly. *Boatmon*, 941 F.3d at 1354-55, 1359-60. As the remanding opinion explained, the *Boatmon* decision clarified (i.e. reexplained) the older *Althen* and *Knudsen* holdings. It did not change or question them. *Kottenstette*, 2020 WL 953484. Specifically, the *Boatmon* Court stressed, citing the 2010 Federal Circuit decision *Moberly v. Secretary of Health & Human Services*, 592 F.3d 1315 (Fed. Cir. 2010), that “[w]e have consistently rejected theories that the vaccine only ‘likely caused’ the injury and reiterated that a ‘plausible’ or ‘possible’ causal theory does not satisfy the standard.” *Boatmon*, 941 F.3d at 1360. Nor would the *Boatmon* panel even have had the authority to overturn *Althen* or *Knudsen* in favor of a heightened burden. See, e.g., *Lumbermens Mut. Cas. Co. v. U.S.*, 654 F.3d 1305, 1313 (Fed. Cir. 2011) (noting that “a panel of this court would lack the authority to eliminate this rule in view of our prior precedents explicitly holding that equitable subrogation only applies to payments made after the obligee receives notice of the default.”); *George E. Warren Corp. v. U.S.*, 341 F.3d 1348, 1351 (Fed. Cir. 2003) (stating that “[w]e cannot simply overrule the *Texport* decision, even if we were persuaded (which we are not) that it is appropriate; to overrule a precedent, the court must rule en banc.”).

In sum, the decision on remand interpreted the remanding opinion as requiring that I apply the *Althen* test and not any heighten burden of proof. Moreover, preponderant evidence of causation-in-fact pursuant to the *Althen* test was clearly the standard applied by the now withdrawn decision on remand. To the extent petitioners argue to the contrary, those arguments challenge the remanding opinion itself, not the decision on remand, and are therefore better addressed by a motion for review and not a motion for reconsideration.

b. Petitioners’ Request to File Additional Evidence Does Not Involve Previously Unavailable Evidence

Nonetheless, motions for reconsideration may also be granted where previously unavailable evidence subsequently becomes available. Here, petitioners’ request to file additional evidence has two distinct aspects. First, petitioners discussed several discrete pieces of evidence within their motion that they request be considered. Second, petitioners broadly requested that entitlement be reopened entirely. However, neither request identifies previously unavailable evidence.

Petitioners discussed three articles attached to their motion as Exhibits 31-33, along with a web printout marked as Exhibit 30, a further study that was not filed, and unspecified CDC Vaccine Information Statements for the DTaP vaccine. (ECF No. 133.) Petitioners urged that these materials included studies that should be viewed as “admissible and persuasive evidence.” (*Id.* at 10.) As noted above, these submissions are in furtherance of petitioners’ assertion that compared to the older DTP vaccine, DTaP “does the same harm only less frequently.” (*Id.* at 6.) Each of the articles petitioners now seek to have considered were published prior not only to the hearing in this case, but prior even to the filing of this case, and were therefore available for filing

at all times during the pendency of this case.⁶ Indeed, petitioners themselves specifically argue that what they are asserting now has been generally accepted in the medical community since 2003. (ECF No. 133, p. 11.)

Further, in reference to the level of proof needed to meet what they characterize as a heightened burden, petitioners also more broadly concluded by remarking that petitioners “should be given the opportunity to submit such proof or to provide expert opinion as to why science deems the conclusions based upon cause and effect to be sound. Petitioner[s] should be granted leave to re-open to do so.” (*Id.* at 15.) However, I provided petitioners an opportunity to explain more specifically what further evidence they wished to file (ECF No. 136) and they identified none.

After respondent provided his response to the motion, I instructed that “[i]n their reply, petitioners shall clarify the scope of their request for leave to file additional evidence. Specifically, if petitioners seek to file any additional evidence beyond what was attached to the motion for reconsideration, petitioners’ reply shall specify what additional evidence petitioners seek leave to file.” (ECF No. 136.) In their reply, petitioners again discussed the same studies cited in their motion for reconsideration, indicating that “petitioner[s] [have] added empirical peer reviewed, thus reputable material which establishes with credible medical research that DTaP still causes the same adverse reactions as DTP.” (ECF No. 137, pp. 6-7.) In closing, petitioners indicated that they “move for reconsideration with the ability to submit additional evidence but also point out that the record fully supports this child’s claim as it establishes that the opinion of Dr. Kinsbourne was ‘sound and reliable.’” (*Id.* at 7.)

In response to my order, petitioners did not identify any additional studies or other materials (previously unavailable or not) to be filed. Nor did they specifically request that they be permitted to file an additional report by Dr. Kinsbourne or any other expert. Nor did they request an opportunity to elicit further testimony from Dr. Kinsbourne. Rather, they reiterated their reliance on the same, previously available, materials discussed above. Accordingly, petitioners have not demonstrated that their broader request to reopen the record on entitlement relates to any previously unavailable evidence.

⁶ As noted in *supra*, note 2, the three studies attached to petitioners’ motion were published between 1999 and 2003. The additional study cited, but not filed, dates from 2002. Although petitioners also cited Vaccine Information Statements, they did not cite any a specific edition. According to the CDC, the current Vaccine Information Statement for DTaP is dated April 1, 2020 (interim) and there have been six prior versions dated August 24, 2018; May 17, 2007; July 30, 2001; August 15, 1997; September 13, 1996; June 10, 1994. See CENTERS FOR DISEASE CONTROL AND PREVENTION, *Dates of Current and Past Vaccine Information Materials*, <https://www.cdc.gov/vaccines/hcp/vis/vis-dates.html> (last accessed on June 1, 2020). Petitioners did not describe any relevant change from among the various editions. An additional undated exhibit (Ex. 30) relates to infantile spasms generally and not to the question of vaccine causation.

c. Petitioners Request to File Additional Evidence Raises No Question of Manifest Injustice and Additional Filings Are Not in the Interest of Justice

Since petitioners do not argue that their request to reopen entitlement relates to evidence that was previously unavailable, this raises two further related questions. First, did petitioners' failure to file this previously available evidence during the entitlement phase of this case nonetheless stem from or represent any manifest injustice? Second, would allowing the filing of such evidence now at this late stage of proceedings be in the interest of justice? In that regard, petitioners argue, as discussed above, that they have been subjected to a heightened burden of proof subsequent to the close of the record on entitlement. (ECF No. 133, p. 15.) Additionally, they further argue, in effect, that the basis for their contention that DTP and DTaP cause the same harm is so well-founded that they were justified in treating the question "lightly" in the first instance and, in fact, that the answer is so uncontroversial as to warrant judicial notice.⁷ (ECF No. 137, p. 5.)

Respondent stresses in his opposition that "a motion for reconsideration should not be used to gain a second opportunity to argue what was already decided." (ECF No. 135, p. 5 (quoting *Chuisano v. Sec'y of Health & Human Servs.*, No. 07-452V, 2013 WL 6234660, at *20 (Fed. Cl. Spec. Mstr. Oct. 25, 2013) (citing *Fillmore Equipment of Holland, Inc. v. United States*, 105 Fed. Cl. 1, 9 (2012))).) Respondent suggests that consideration of further evidence is not warranted both because petitioners' burden of proof has not changed and also because petitioner has not identified any evidence that was previously unavailable. (ECF No. 135, pp. 4-5.) Moreover, respondent argues that "petitioners had every opportunity to develop the record in this case" and further contends that petitioners' motion is "without legal or factual merit, and the relief requested should therefore be denied." (*Id.* at 1, 4.)

Respondent's position is supported by several significant points. First, petitioners' underlying rationale for reopening the record on entitlement is that the burden of proof changed as a result of the remanding opinion. However, for all the reasons described in Section IV(a), above, I conclude that this rationale is unpersuasive. Moreover, in contrast to petitioners' suggestion that they were justified in treating the issue "lightly," respondent litigated the questions now at issue throughout the entitlement phase of this case. Dr. Zempel explicitly raised the issue of the limitations of evidence relating to DTP versus DTaP in his first expert report accompanying respondent's Rule 4 report and further specifically noted that Dr. Kinsbourne "does not provide any evidence from this era or for any time since then that vaccinations (and specifically DTaP vaccination) cause infantile spasms or that vaccinations worsen outcome in infantile spasms." (Ex. A, p. 6.) Respondent further

⁷ In raising these arguments, petitioners' motion papers largely discuss seizures generally without distinguishing between febrile or afebrile seizures on the one hand or specific seizure disorders such as infantile spasms on the other.

argued this point in his prehearing submission. (ECF No. 56, p. 3.) Accordingly, petitioners' have little basis for contending that the issues raised by the remanding opinion, or the need to establish that DTaP (or any of C.K.'s other vaccinations), as opposed to DTP, can cause her infantile spasms, were unanticipated.

Petitioners repeatedly assert in their motion papers that the connection between DTaP and seizures is "generally accepted by medicine" and further that "this court should take judicial notice of the fact that all pertussis vaccine can cause seizures." (ECF No. 133, p. 11.) Taken at face value, that does suggest petitioners felt, however unadvisedly, that the additional evidence they now wish to file was unnecessary. However, this does not alone provide a basis for reopening entitlement. See, e.g., *Cozart v. Sec'y of Health & Human Servs.*, No.00-590V, 2015 WL 6746499, at *4 (Fed. Cl. Spec. Mstr. Oct. 15, 2015) (explaining that "[t]he additional evidence that petitioners presented is not new evidence; rather, it is an article that was available to petitioners at the time this case went to hearing. The argument that petitioners did not deem this article relevant until the undersigned issued her decision is not proper grounds for reconsideration of the undersigned's decision."). It is, of course, indisputable that in all events each petitioner in each case bears a burden of proving all elements of compensation by preponderant evidence. 42 U.S.C. §300aa-13(1)(a).

Furthermore, respondent clearly put petitioners on notice regarding this issue. In respondent's prehearing brief, respondent's counsel wrote:

[I]t is not accepted that DPT, let alone DTaP, can cause seizure disorders. In fact, this special master [referring to Special Master Millman] 'has held repeatedly that DPT does not cause afebrile seizures, based on the NCES, the IOM and other literature.' See e.g., *Borin v. HHS*, No. 99-491V, 2003 WL 21439673, at *11 (Fed. Cl. May 29, 2003). Most importantly, however, is the fact there is no reliable evidence that DTaP causes infantile spasms, and that is what is required for petitioners to prevail here.

(ECF No. 56, p. 3.) Respondent further explained that, notwithstanding a prior status conference in which Special Master Millman appeared receptive to reliance on DTP studies in this case, respondent would continue to object, stating that "[r]espectfully, it is respondent's position that there is no evidence that DTaP vaccine causes infantile spasms." (*Id.* at n.3.)

Moreover, even if petitioners did not wish to file additional evidence at that time, the hearing itself also clearly presented both the need and opportunity for cross-examination on these issues. As noted above, respondent's expert Dr. Zempel raised in his first report that he did not agree that evidence relating to DTP could be applied to the DTaP vaccine. (Ex. A, p. 6-8.) Moreover, during the hearing, he specifically testified that he is unaware of anyone in the medical community apart from Dr. Kinsbourne who agrees that any vaccines can cause infantile spasms. (Tr. 176.) Despite this, petitioners' counsel declined to cross-examine Dr. Zempel regarding the

apparent mismatch between his opinion and what petitioners now argue is generally accepted medicine. (Tr. 182.) Petitioners' cross-examination of Dr. Zempel was limited to one unrelated question. (*Id.*)

Nonetheless petitioners assert an unlimited right to supplement the record prior to entry of judgment. Specifically, petitioners' quote the following from the Vaccine Act: "the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court." See 42 U.S.C. §300aa-13(b)(1). This statement, however, relates specifically to any necessary updates regarding the evolution in petitioners' *own* medical condition up to the time of judgment. It does not preclude the special master or the court from closing the record in advance of resolution of the case. Such an interpretation of the statute would be wholly unworkable and contrary to the longstanding Vaccine Rules and practice. *E.g.*, *Sword v. U.S.*, 44 Fed. Cl. 183, 190 (1999) (explaining that "judicial officers conducting evidentiary hearings—trials—are afforded great latitude on how they administer the proceedings in their forum. See Vaccine Rules 3 and 8. That applies to petitions for reconsideration of rulings, and proffers designed to supplement the factual record after the record is closed."); *but see Shaw v. Sec'y of Health & Human Servs.*, 91 Fed. Cl. 715, 720 (2010) (holding that "[i]n light of the Vaccine Act's bias toward compensation, we find it in the interest of justice to remand this case to the special master to consider the new evidence."). Rather, special masters have authority to receive evidence based on the specific circumstances of each case and "governed by principles of fundamental fairness to both parties."⁸ Vaccine Rule 8(a)-(b)(1).

In light of all of the above, I conclude that there has been no manifest injustice in this case and further that it would not be in the interest of justice to reopen the entitlement record for purposes of considering the additional material discussed in petitioners' motion for reconsideration and/or any further unspecified evidence petitioners may intend to file at a later date. The factors described above compellingly suggest petitioners had a full and fair opportunity to meet their appropriate burden of proof. Accordingly, no further evidentiary filings will be allowed at this late stage in the litigation.

⁸ Notably, while some prior cases have noted this program's tilt toward compensating petitioners, Vaccine Rule 8(b)(1) requires that that all evidence be considered in "fundamental fairness to *both parties*" (emphasis added). Petitioners argue that respondent's position in this case is inconsistent with the clear intent of the program and evidence that this program "has gone off the rails." (ECF No. 137, pp. 4-5.) I disagree. Although petitioners may disagree with respondent's position, from my review of the record, respondent fairly and consistently raised during the entitlement phase of this case the issues that eventually came to be at issue on this motion. Moreover, respondent and his counsel have a role to play in every case in this program, both compensable and non-compensable alike. There should be at least some competing hesitation in forcing respondent to devote program resources to re-litigating issues properly raised in the first instance.

d. Petitioners' remaining arguments are unavailing

Finally, I note that I have reviewed and considered petitioners' remaining arguments addressing the substance of Dr. Kinsbourne's opinion. However, none of these arguments favor a reopening of the evidentiary record or otherwise merit reconsideration of the previously issued decision on remand. As noted above, reconsideration "must be based 'upon manifest error of law, or mistake of fact, and is not intended to give an unhappy litigant an additional chance to sway the court.'" *Prati*, 82 Fed. Cl. at 376 (quoting *Fru-Con Constr. Corp.*, 44 Fed. Cl. at 300).

Petitioners' arguments do not describe any mistake of fact or law, but rather seek to reargue points addressed by the prior decision on remand and express petitioners' disagreement with the outcome of the decision. For example, petitioners ascribe error based on the failure to recognize, as they assert in their motion, that Dr. Kinsbourne's testimony was "fully supported by the peer reviewed medical literature cited in his report." (ECF No. 133, p. 6.) However, this was addressed in the decision on remand, which explained that Dr. Kinsbourne testified that he could not recall citing any literature implicating vaccines in his proposed theory (Tr. 78) and in his supplemental report conceded that "scientific proof is lacking" for his specific contention that vaccines could cause infantile spasms (Ex. 6, p. 1).

Additionally, petitioners have largely, if not entirely, focused on arguments pertaining to their medical theory pursuant to *Althen* prong one. However, the decision on remand had also found that there are significant factual issues relating to *Althen* prong two.

V. Conclusion

Petitioners' motion for reconsideration is granted to the extent of having withdrawn the April 27, 2020 decision on remand in order to consider petitioners' arguments on reconsideration; however, petitioners' arguments are unpersuasive. Petitioners' further request to reopen the evidentiary record on entitlement is denied. Accordingly, the record on entitlement will not be reopened and a separate, superseding decision will be issued pursuant to Vaccine Rule 10(e). However, that decision will not reach a conclusion different from the now withdrawn April 27, 2020 decision on remand.

IT IS SO ORDERED.

s/Daniel T. Horner

Daniel T. Horner
Special Master